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In The

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
AND PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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SUMMARY OF THE ARGUMENT

This case is unlikely to have far-reaching effects: It is limited to Michigan drug-injury cases brought within the Second Circuit, in which a plaintiff can make a showing of fraud on the FDA; the statute at issue is subject to repeal by a bill that has passed one House of the Michigan Legislature and is pending in the other; and there is no evidence of any real imposition on the FDA from the operation of the Michigan statute.

The preemption issue herein is intertwined with whether the fraud-on-the-FDA exception is severable from the statutory grant of immunity for FDA-approved drugs, a state law question on which the Michigan Supreme Court has not yet ruled. Application of established Michigan caselaw indicates that the exception is not properly severable, so that the statute must be considered as a whole in addressing preemption.

The Second Circuit properly distinguished *Buckman* on the grounds that the present case involves (i) state regulation of tort law affecting health and safety, as to which the presumption against preemption applies (rather than an attempted use of state law to police fraud on the FDA); (ii) alleged violation of state common law duties, rather than solely the federal duty of candor to the FDA; and (iii) invocation of fraud on the FDA to rebut an affirmative defense, rather than as an element of a claim.

ARGUMENT

1. The Second Circuit's preservation of drug product liability claims in Michigan will not have far-reaching effects.

The present case concerns a Michigan law which provides for a complete defense from product liability for the sale of FDA-approved drugs in Michigan. Its reach is quite limited: the Second Circuit's decision herein will directly affect only drug liability cases (1) brought in a federal court in the Second Circuit, (2) where Michigan law applies, and (3) where the plaintiff can prevail on a fraud-on-the-FDA defense to the statutory immunity. Such cases are likely to be rare.

Indeed, the issue presented herein may vanish entirely, as the Michigan legislature is currently considering repeal of the very statute at issue. **A bill to strike M.C.L. § 600.2946(5) has passed the Michigan House of Representatives, and is pending in the Senate,** where it has been referred to the Judiciary Committee.[1]

Assuming the act remains in effect, the fraud-on-the-FDA exception in the Michigan statute will only come into play when a Michigan resident who claims to be injured by an FDA-approved drug learns of adverse trial results that were withheld from the FDA. As a practical matter, plaintiffs will be unable to make a colorable claim of fraud-on-the-FDA in run-of-the-mill cases,[2] and the issue will

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[1] *See* Michigan House Bill 4044 (2007), reproduced on the Michigan Legislature's website at http://www.legislature.mi.gov/documents/2007-2008/billengrossed/House/htm/2007-HEBH-4044.htm.

[2] Thus, for example, the plaintiffs in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965-66 (6th Cir. 2004), one of the very few reported cases decided under M.C.L. § 600.2946(5), "had offered no

(Continued on following page)

likely be limited to groups of cases where widespread problems lead to withdrawal from the market of a popular drug such as Rezulin or Vioxx, with attendant publicity.

Even in cases in which the fraud-on-the-FDA exception is asserted, the potential for interference with the FDA's federal functions is more theoretical than real. The FDA can avoid being "dragged into" the dispute by "declin[ing] to permit its employees to testify about their official duties, pursuant to 21 C.F.R. § 20.1." Petition at 25.[3] As to the Petition's professed concern that absent FDA testimony, juries might speculate about how the FDA would have reacted to additional information, *see* Petition at 25, it is not apparent how such speculation, even if ill-informed, could hurt the FDA or its regulatory processes.

Moreover, as the Second Circuit pointed out, the potential burdens on the FDA from a fraud-on-the-FDA exception to statutory immunity for FDA-approved drugs are not materially different than the potential burdens from the residual common law rule under which such matters are admissible but not necessarily determinative. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 (2d Cir. 2007), App. 25a. Indeed, the formulation adopted by the Sixth Circuit in *Garcia*, requiring a finding of fraud by the FDA as a prerequisite to maintaining a product

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proof of fraud" and "did not seek to satisfy the statutory exception". Petition at 18.

[3] Petitioners object that "courts do not always honor FDA's decisions in this regard", citing a district court decision denying an FDA motion to quash a subpoena. Petition at 25. However, this seems more like a reason to review that district court's discovery ruling than to review the Second Circuit's preemption decision herein.

liability action under the Michigan statute,[4] creates a potential for far greater burdens on the FDA. Rather than merely having the information submitted to it and its decision-making thereon reviewed by a court, the FDA could be saddled with the task of adjudicating fraud claims pursuant to citizen petitions in every civil case to which the Michigan act applies, whereupon the FDA would be required in each case to keep a formal record, furnish a response within 180 days, decide upon further petitions for reconsideration or stay, and ultimately face court review under the Administrative Procedure Act. *See* 21 C.F.R. § 10.30, App. 131a-137a. In effect, the position urged by Petitioner could make the FDA decide parties' dispute as to fraud, rather than leaving such private disputes to the court system.

Petitioners have made no showing that the issues implicated by M.C.L. § 600.2946(5), or by the differing preemption analyses of the Second and Sixth Circuits, will have any real or substantial disruptive effect on the FDA or the courts. If such issues become burdensome in fact, there will *ipso facto* be further opportunities for this Court to review them. As matters stand now, however, this case is unworthy of a grant of *certiorari*.

2. The exception for fraud on the FDA is not severable from the presumption of non-defectiveness for FDA-approved drugs.

A full analysis of the preemption issue herein is inextricably intertwined with consideration of whether the fraud-on-the-FDA exception is severable from the grant of

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[4] *See Garcia*, 385 F.3d at 966.

immunity for FDA-approved drugs – which is a question of Michigan law on which the Michigan Supreme Court has not spoken.

The difference between the approaches of the Second Circuit herein and the Sixth Circuit in *Garcia* turns on the courts' respective characterizations of the potentially preempted state law provision. The Sixth Circuit considered whether Michigan's fraud-on-the-FDA exception to statutory immunity, standing alone, is preempted, while the Second Circuit considered whether Respondents' "common law claims – preserved by Michigan's exception" are preempted. *Compare Garcia*, 385 F.3d at 965-66, *with*, *Desiano*, 467 F.3d at 89, App. 9a.[5] Determination of which characterization is appropriate requires consideration of whether the exception is severable from the non-liability provision. If the exception is bound up with the grant of immunity, so that M.C.L. § 600.2946(5) must be considered as a whole, then the statute is manifestly within the core of traditional state law authority over health and safety. *See* M.C.L. § 600.2946(5) (providing that FDA-approved drug is "not defective or unreasonably dangerous"). *Cf. Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 134 (Mich. 2003) (explaining that M.C.L. § 600.2946(5) directs courts to adopt "the FDA conclusion regarding the safety and efficacy of a drug").

Under a proper application of Michigan law, the fraud-on-the-FDA exception is not severable from the grant of

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[5] *See also, e.g.*, *Desiano*, 467 F.3d at 87, App. 4a ("The question presented by this appeal is whether . . . federal law also preempts traditional common law claims that survive a state's legislative narrowing of common law liability through a fraud exception to that statutory limitation.").

immunity for FDA-approved drugs. Consequently, a preemption analysis should consider the statute as a whole, and the Second Circuit was therefore correct in applying a presumption against preemption.

The *Garcia* court's holding that the exception for fraud on the FDA is severable from the remainder of M.C.L. § 600.2946(5) – which provides that an FDA-approved drug is not defective or unreasonably dangerous and that a manufacturer or seller of such a drug is generally not liable in a product liability action – was based upon a superficial and erroneous analysis. The sole Michigan authorities relied on in *Garcia* are a statute generally declaring acts to be severable (M.C.L. § 8.5) and a 1971 case described as "upholding the remainder of the enacted law because it is 'otherwise complete in itself and capable of being carried out without reference to the unconstitutional' section". *Garcia*, 385 F.3d at 967, quoting *Maki v. East Tawas*, 188 N.W.2d 593, 596 (Mich. 1971). However, the severability statute is expressly limited to remaining portions of the act "which can be given effect without the invalid portion", and "are not determined by the court to be inoperable". M.C.L. § 8.5.[6] Here, longstanding

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[6] MCL § 8.5 provides:

> In the construction of the statutes of this state the following rules shall be observed, unless such construction would be inconsistent with the manifest intent of the legislature, that is to say:
>
> If any portion of an act or the application thereof to any person or circumstances shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application, provided such remaining portions are not determined by the court to be inoperable, and to this end acts are declared to be severable.

principles of Michigan law, as well as basic fairness, require that the grant of non-liability for sale of FDA-approved drugs cannot be given effect, and must be found inoperable, in the absence of the exception which is part and parcel of the grant.

The *Garcia* opinion held that the exception in M.C.L. § 600.2946(5) is not preempted in all possible applications, but remains valid in cases where "the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Garcia*, 385 F.3d at 966 (italics in original). The opinion proceeded to decide that the Michigan legislature would prefer "immunity absent a finding of bribery or fraud by the Federal Government" to "no immunity" for FDA-approved drugs. *Id.* at 967. Far from being supported by Michigan caselaw, the *Garcia* court's method of proceeding is actually expressly disapproved in *Maki*, the sole Michigan case relied upon.

Maki involved a grant of governmental immunity from tort liability. Although *Maki* did indeed hold that other sections of the same act were severable, upon determining that the broad grant of immunity for all torts could not be upheld, it declined to preserve the constitutionality of the section in question by limiting it to immunity for negligence, reasoning that to do so "would require this Court to engage in judicial legislation." 188 N.W.2d at 595. According to *Maki*, the duty of the courts "is to construe what [the legislature] has written. After all, [the legislature] expresses its purpose by words. It is for us to ascertain – neither to add nor to subtract, neither to delete nor to distort." *Id.* at 596, quoting *Cases of Jam v. United States*, 340 U.S. 593, 596 (1951). Thus, the *Maki* court refused to engage in the process followed by the Sixth Circuit in *Garcia*. Rather than speculating about which

course the Michigan legislature would "rather" between two alternatives that were not before it, the *Maki* court simply observed that "[w]e cannot say that the legislature clearly understood" the issue before the court, and "we cannot determine how they would have voted had they known". The same is plainly true here.

Rather than speculating as to how the Michigan legislature would prefer the courts to rewrite the statute, courts should instead limit their inquiry into whether the remaining portions of the statute as written truly stand alone, or are intertwined with the invalid portion. Under Michigan law,

> To be capable of separate enforcement, the valid portion of the statute must be independent of the invalid sections, forming a complete act within itself. After separation of the valid parts of the enactment, the law enforced must be reasonable in view of the act as originally drafted.

Pletz v. Secretary of State, 336 N.W.2d 789, 809 (Mich. App. 1983) (footnotes omitted). As explained in a leading Michigan case:

> Whether the other parts of the statute must also be adjudged void because of the association must depend upon a consideration of the object of the law, and in what manner and to what extent the unconstitutional portion affects the remainder. . . . Where, therefore, a part of a statute is unconstitutional, that fact does not authorize the courts to declare the remainder void also, unless all the provisions are connected in subject matter, depending on each other, operating together for the same purpose, or otherwise so connected together in meaning, that it cannot be presumed the legislature would have passed the

> one without the other.... The point is ... whether they are essentially and inseparably connected in substance.... [I]f they are so mutually connected with and dependent on each other, as conditions, considerations, or compensations for each other, as to warrant the belief that the legislature intended them as a whole, and if all could not be carried into effect the legislature would not pass the residue independently, then if some parts are unconstitutional, all the provisions which are thus dependent, conditional, or connected must fall with them.

People v. McMurchy, 228 N.W. 723, 727 (Mich. 1930) (emphasis added; internal quotation marks and citation omitted). *See also Seals v. Henry Ford Hospital*, 333 N.W.2d 272 (Mich. App. 1983) (quoting part of foregoing passage from *McMurchy*).

In the present cases, it is clear that the fraud-on-the-FDA exception in M.C.L. § 600.2946(5) "affects", "depends upon", and is "essentially and inseparably connected" to the subject of the remainder, so that it cannot be excised without detracting from the apparent legislative intent. Subsection (5) has a single object – viz, the creation of a specific rebuttable presumption – which requires both the non-liability and the exception to operate as intended. The exception serves as a "condition, consideration or compensation" for the non-liability, and retaining the latter without the former would not be "reasonable in view of the act as originally drafted".

The Michigan legislature clearly intended that persons injured by FDA-approved drugs have a means to rebut the presumption that such drugs are not defective or unreasonably dangerous. Upon striking down the means of

rebuttal prescribed in the statute, the Sixth Circuit cavalierly substituted a different method with no showing of efficacy.[7] Long ago, the Michigan Supreme Court addressed a similar situation where the legislatively-prescribed means of rebutting a presumption was found to be invalid:

> The legislature, in making the rule that a deed recorded two years should be conclusive, did not design to leave parties without the means of testing it in the mean time. The remedy they provided was held void.... There is no other adequate remedy, and we think the whole statute was designed to go together; so that, the remedy failing, the whole provision falls with it.

Quinlon v. Rogers, 12 Mich. 168, 170 (1863). The same result should obtain here.

Notwithstanding the *Garcia* opinion's lack of grounding in Michigan caselaw, Petitioners contend that its interpretation of the Michigan statute is entitled to deference because Michigan is within the Sixth Circuit's

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[7] The inefficacy of the Sixth Circuit's formulation was recognized by the District Court herein:

> Now, there is no doubt that that outcome as a matter of social policy could perhaps be criticized by reasonable people. I assume ... that the FDA simply does not go around suing people or otherwise seeking to obtain or making findings that drug manufacturers have committed fraud in the new drug application process.
>
> The 6th Circuit's conclusion, therefore, puts plaintiffs who are subject to the Michigan statute in a pretty difficult spot. It may be that that is an undesirable outcome and it may well be that Congress and/or the Michigan legislature ought to address it....

App. 35a.

territory.[6] *See* Petition at 18-19 & n.9, citing *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981). That case recognized, however, that "[a] federal court in another circuit would be obliged to disregard a state law holding by the pertinent court of appeals if persuaded . . . that prior state court decisions had been inadvertently overlooked by the pertinent court of appeals." *Factors*, 652 F.2d at 283. Respondents submit that the Sixth Circuit in *Garcia* overlooked the Michigan caselaw directing that interconnected provisions may not be severed. Moreover, even if *Factors* would bind the Second Circuit, there is no principle requiring this Court to defer to the Sixth Circuit's flawed analysis, as Michigan is equally within the territory of this Court.

3. The Second Circuit's decision herein is not inconsistent with *Buckman*.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that an asserted state law cause of action for fraud on the FDA is impliedly preempted because it conflicts with the FDA's jurisdiction to police fraud against itself. *Buckman* involved an allegation that bone screws that were not unreasonably dangerous in themselves had been submitted to the FDA for approval based on inaccurate statements as to their intended use. Thus, the only duty claimed to have been breached was a federal duty to provide accurate information to the FDA,

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[6] *Garcia* was followed by the Michigan Court of Appeal in *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628515 (Mich. Ct. App. June 13, 2006), App. 213a. However, this unpublished *per curiam* opinion did not address severability.

rather than any general state law duty to refrain from marketing an unreasonably dangerous product.

The *Buckman* opinion distinguished *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), because the claims in *Buckman* were not grounded in the states' traditional regulation of product liability: "in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' *Medtronic, 518 U.S. at 485* – no presumption against pre-emption obtains in this case." *Buckman*, 531 U.S. at 348.[9] The *Buckman* opinion went on to emphasize the distinction between the claims therein based solely on violation of federal law, and claims based on state product liability law that also involve a violation of federal law:

> [I]t is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.

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[9] In *Medtronic*, this Court held that, in view of a strong presumption against federal preemption in areas of traditional local concern, state tort claims for injuries caused by FDA-approved medical devices are not generally preempted. *See Medtronic*, 518 U.S. at 475 (1996) (recognizing that public health and safety are "primarily, and historically, . . . matter[s] of local concern") (quoting *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985)) (ellipsis and brackets supplied by *Medtronic* opinion); *Id.* at 485 ("In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). *See also, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992) (construing preemption provisions "in light of the presumption against the pre-emption of state police power regulations").

> In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. . . . .
>
> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case.

Id. at 352-53 (citation omitted).

In the present case, the Second Circuit distinguished *Buckman* on three grounds. First, as to the presumption against preemption the court held:

> The Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to "regulat[e] matters of health and safety," which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest. As a result, while there may be reasons to override that presumption, the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*.

Desiano, 467 F.3d at 94, App. at 19a (citation omitted).

Second, the Second Circuit distinguished *Buckman* on the ground that the present case involves a claimed violation of traditional state common law tort duties, rather than solely the federal duty of candor to the FDA as in *Buckman*:

> These pre-existing common law claims survive under M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike

> the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA. Given *Buckman's* explanation of *Medtronic*, *Buckman* cannot be read as precluding such pre-existing common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA.

Desiano, 467 F.3d at 95, App. 21a-22a 9 (italics in original).

Third, the Second Circuit distinguished *Buckman* on the ground that in the present case fraud on the FDA serves only to rebut a statutory affirmative defense, rather than to supply an element of a claim. The court explained:

> Finding preemption of traditional common law claims where fraud is not even a required element – but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law – would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect.

Desiano, 467 F.3d at 96, App. 24a.

Each of these three distinctions is well grounded, and has not meaningfully been challenged by Petitioners in their present Petition for a writ of *certiorari*.

CONCLUSION

For the foregoing reasons, Petitioners' Petition for a writ of *certiorari* should be denied.

Respectfully submitted,

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